

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015-JLH
)	
SAREPTA THERAPEUTICS, INC.,)	DEMAND FOR JURY TRIAL
)	
Defendant.)	
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)	
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.,)	
)	
Plaintiff/Counter-Defendants.)	

THE COURT'S PRELIMINARY JURY INSTRUCTIONS

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I. INTRODUCTION AND ROLE OF THE JURY

Members of the Jury: Now that you have been sworn in, I have the following preliminary instructions for guidance on your role as jurors in this case.

These instructions are intended to introduce you to the case and the law that you will apply to the evidence you will hear. Also, because this case involves patents, I will give you some preliminary instructions regarding patents to assist you in discharging your duties as jurors. I will give you more detailed instructions on the law at the end of the trial.

You will hear evidence, decide what the facts are, and then apply those facts to the law that I will give to you. You and only you will be the judges of the facts. I play no part in judging the facts. My role is to be the judge of the law. I make whatever legal decisions have to be made during the course of the trial, and I will explain to you the legal principles that must guide you in your decisions. You must follow that law whether you agree with it or not. It is important that you perform your duties fairly. Do not let any bias, sympathy, or prejudice influence your decision in any way. Nothing I may say or do during the course of the trial is intended to indicate what your verdict should be.

II. UNITED STATES PATENTS

This case involves patents. To help you understand what patents are, the role of the Patent Office, and why disputes over patents arise, you will now be shown a video. This video was prepared by the Federal Judicial Center, not the parties in this case, to help introduce you to the patent system. During the video, reference will be made to a sample patent, a copy of which is in your juror notebook. The video will run for approximately 17 minutes. At the conclusion of the video, I will provide you with additional instructions.

[The video will be played.]

III. OVERVIEW OF THE CASE

To help you follow the evidence, I will now give you a summary of the positions of the parties.

The parties in this case are Nippon Shinyaku Co., Ltd., NS Pharma, Inc., Sarepta Therapeutics, Inc., and the University of Western Australia. Unless otherwise specified, I may refer to Nippon Shinyaku Co., Ltd. as “Nippon Shinyaku,” and to NS Pharma, Inc. as “NS Pharma.” I may refer to Sarepta Therapeutics, Inc. as “Sarepta” and to the University of Western Australia as “UWA.” There are claims for which Nippon Shinyaku is the plaintiff and Sarepta is the defendant. There are also claims for which Sarepta and UWA are the plaintiffs and Nippon Shinyaku and NS Pharma are the defendants.

Nippon Shinyaku alleges that Sarepta infringes three U.S. Patents: U.S. Patent Nos. 10,385,092; 10,407,461; and 10,662,217. Unless otherwise specified, I may refer to these patents as the “NS Patents.” Sarepta acknowledges that it infringes the asserted claims of the NS Patents but contends that those claims are invalid.

Sarepta and UWA allege that Nippon Shinyaku and NS Pharma infringe U.S. Patent No. 9,994,851. Unless otherwise specified, I may refer to this patent as the “Wilton Patent.” Nippon Shinyaku and NS Pharma acknowledge that they infringe the asserted Wilton Patent claim but contend that the claim is invalid.

For your convenience, the parties and I will often refer to the patents by the last three digits of the patent number. For example, U.S. Patent No. 10,385,092 will often be referred to as the ’092 Patent or U.S. Patent No. 9,994,851 will often be referred to as the ’851 Patent.

Nippon Shinyaku filed suit in this court seeking money damages from Sarepta for infringing the NS Patents by making, importing, using, selling, or offering for sale, products and methods that are covered by the asserted claims of the NS Patents.

Sarepta and UWA filed suit in this court seeking money damages from Nippon Shinyaku and NS Pharma for infringing the Wilton Patent by making, importing, using, selling, or offering for sale, products that are covered by the asserted claim of the Wilton Patent.

The patents in this lawsuit relate to the treatment of Duchenne Muscular Dystrophy, which the parties and I will often refer to as “Duchenne” or “DMD.” Sarepta’s VYONDYS 53[®] product infringes the NS Patents. Nippon Shinyaku and NS Pharma’s VILTEPSO[®] product infringes the Wilton Patent.

Nippon Shinyaku and Sarepta argue that the claims of each other’s patents are invalid. I will instruct you later as to the ways in which a patent may be invalid. In general, however, a patent is invalid if it is obvious in view of the state of the art at the relevant time, or if the description in the patent does not meet certain requirements.

Your job will be to decide whether or not the asserted claims of the NS Patents and Wilton Patent are invalid. If you decide that any of the asserted NS Patent claims are not invalid, you will then need to decide any money damages to be awarded to Nippon Shinyaku to compensate it for the infringement. Likewise, if you decide that the asserted claim of the Wilton Patent is not invalid, you will then need to decide any money damages to be awarded to Sarepta and UWA to compensate them for the infringement.

You will also need to make a finding as to whether any infringement was willful. I will give you more detail about willful infringement at the end of the trial. If you decide that any infringement was willful, that decision should not affect any damages award you give. I will take willfulness into account later.

IV. EVIDENCE

The evidence from which you will find the facts will consist of the testimony of witnesses, documents, and other things received as evidence. In addition, the evidence may include certain facts that are formally agreed to by the parties, and any facts I instruct you to accept as true.

Certain things are not evidence. I will list those things for you now:

1. Statements, arguments, questions, and comments by lawyers are not evidence.
2. Demonstratives are not evidence.
3. Exhibits that are identified by a party but not offered or received in evidence are not evidence.
4. Objections are not evidence. Lawyers have an obligation to their clients to make an objection when they believe testimony or exhibits being offered into evidence are not proper under the Rules of Evidence. You should not be influenced by a lawyer's objection or by my ruling on the objection. If I sustain or uphold the objection to a question or an exhibit, you must ignore the question or the exhibit. If I overrule an objection and allow the matter into evidence, you must treat the testimony or document as you would any other evidence. If I instruct you during the trial that some item of evidence is admitted for a limited purpose, you must follow that instruction and consider that evidence for that purpose only. If this does occur during the trial, I will try to clarify this for you at that time.
5. You should not consider testimony and documents I have excluded or stricken from the record and not admitted into evidence or told you to disregard.

6. Anything you see or hear about this case outside the courtroom is not evidence and must be disregarded. You are to decide this case solely on the evidence presented here in the courtroom.

Finally, some of you may have heard the phrases or terms “direct evidence” and “circumstantial evidence.” Direct evidence is direct proof of a fact, such as testimony of an eyewitness. Circumstantial evidence is proof of facts from which you may infer or conclude that other facts exist. For example, the fact that it was raining outside could be proven directly (“I see it raining”) or circumstantially (“someone walks into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella”). Do not be concerned about whether evidence is “direct evidence” or “circumstantial evidence.” You should consider and weigh all of the evidence that is presented to you. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion. I will give you further instructions on these as well as other matters at the end of the case but have in mind that you may consider both kinds of evidence.

V. BURDENS OF PROOF

In any legal action, facts must be proven by a required standard of evidence known as the “burden of proof.” In a case such as this, there are two different burdens of proof that are used. The first is called “preponderance of the evidence.” The second is called “clear and convincing evidence.”

Nippon Shinyaku has the burden of proving the amount of any monetary damages associated with its patent infringement claims by a preponderance of the evidence. Sarepta and UWA have the burden of proving the amount of any monetary damages associated with its patent infringement claims by a preponderance of the evidence. That burden of proof means that the parties have to prove to you, in light of all the evidence, that what they claim is more likely true than not true.

In addition, NS and Sarepta are each challenging the validity of the other side’s asserted patents. A party challenging the validity of a patent has the burden to prove that the asserted claims are invalid by clear and convincing evidence. Clear and convincing evidence means that it is highly probable that the fact is true. Proof by clear and convincing evidence is a higher burden of proof than a preponderance of the evidence.

You may have heard of the “beyond a reasonable doubt” burden of proof from criminal cases. That requirement is the highest burden of proof in our judicial system. It applies only in criminal cases and has nothing to do with a civil case like this one. You should therefore not consider it in this case.

VI. WITNESSES

You are the sole judges of each witness's credibility. It will be up to you to decide which witnesses to believe, which witnesses not to believe, and how much of any witness's testimony to accept or reject. You may consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testify. What is more important is how believable the witnesses were and how much weight you think their testimony deserves.

This instruction applies to all witnesses, including expert witnesses.

VII. EXPERT TESTIMONY

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession, or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience. In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

VIII. DEPOSITION TESTIMONY

I will now talk about the form of some of the evidence you will hear during trial. You may hear witnesses testify through deposition testimony. A deposition is the sworn testimony of a witness taken before trial. The witness is placed under oath and swears to tell the truth, and lawyers for each party may ask questions. A court reporter is present and records the questions and answers. The deposition may also be recorded on videotape.

Deposition testimony is entitled to the same consideration, and is to be judged, insofar as possible, in the same way as if the witness had been present in the courtroom to testify.

IX. ADMITTED FACTS

The parties have stipulated that certain facts are true, and those admitted facts may be read to you during trial. You must treat these admitted facts as having been proven for purposes of this case.

X. DEMONSTRATIVES

Certain charts and summaries may be shown to you in order to help explain the facts disclosed by the books, records, or other underlying evidence in the case. Those charts or summaries are called demonstratives and are used for convenience. They are not themselves evidence or proof of any facts. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the documents, testimony, or other underlying evidence. Demonstratives are not admitted into evidence and should not be considered as evidence.

XI. NOTETAKING

You have been given a notebook that contains the following:

- A copy of these preliminary jury instructions
- A copy of the sample patent referenced in the video introducing you to the patent system
- Copies of the NS Patents and the Wilton Patent; and
- A glossary of abbreviations that may be used in this case.

You have also been given a notepad and a pen. If you wish, you may, but are not required to, take notes throughout the case, including during the opening statements of the attorneys at the outset of the case, the presentation of the evidence, the arguments of the attorneys at the end of the case, and during my instructions to you on the law. Notes may be helpful to you because at the end of the trial, you must make your decision based on what you recall of the evidence. You will not have a written transcript to consult, and it may not be practical for the court reporter to read back lengthy testimony. Therefore, you should pay close attention to the testimony as it is given. I do not suggest that you look to your notetaking as a substitute for a written transcript. Instead, as you listen to the testimony, keep in mind that you will be relying on your recollection of the testimony during your deliberations.

If you do take notes, please keep them to yourself until you and your fellow jurors go to the jury room to decide this case. Do not let notetaking distract you to the point that you miss hearing other testimony from the witness. Your notes are only a tool to aid your own individual memory, and you should not compare your notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are

not evidence and are not a complete outline of the proceedings or a list of the highlights of the trial. Do not use your notes, or any other juror's notes, as authority to persuade fellow jurors.

During the trial, documents or other physical items may be received into evidence. However, you will not be supplied beforehand with a list of exhibits that will be received into evidence. Therefore, you may wish to make notes about the exhibits, especially their description and number, so that you can refer to those exhibits while you are deliberating. You will be given a copy of every admitted exhibit to take to the jury room to use during deliberations.

When we take our recess each day for the lunchtime break and when we take our recess each night, please take your notes to the jury room and leave your notes there. Do not take your notes away from the court at any time. No one will read your notes but you. Your notes will be destroyed after the trial is over.

At the end of the trial, you must make your decision based on what you recall of the evidence. So, above all, your memory will be your greatest asset when it comes time to deliberate and render a decision in this case.

XII. DUTY OF THE JURY

It will be your duty to find what the facts are from the evidence as presented at trial. You, and you alone, are the judges of the facts. You will have to apply those facts to the law as I will instruct you at the close of evidence. You must follow that law whether you agree with it or not. Nothing I say or do during the course of the trial is intended to indicate what your verdict should be.

XIII. CONDUCT OF THE JURY

Now a few words about your conduct as jurors.

First, until you have heard all of the evidence and retired to the jury room to deliberate after closing arguments, you are not to discuss the case with anyone, not even among yourselves during the trial. If any lawyer, party, or witness does not speak to you when you pass in the hall, ride the elevator, or the like, it is not because they are being rude, but rather because they are not supposed to talk with you, nor you with them. If anyone should try to talk to you about the case, please bring it to my attention promptly.

Second, do not read or listen to anything touching on this case that is not admitted into evidence. By that, I mean, if there is a newspaper or internet article or television or radio report relating to this case, do not read the article or watch or listen to the report.

Third, do not try to do any research or investigate the case on your own. Let me elaborate. During the course of the trial, you must not conduct any independent research about the case, the matters in the case, the technology involved in the case, or the individuals or entities involved in the case. In other words, you should not perform “Google” or other web-based or AI searches, consult dictionaries or reference materials (in print, electronic, or other format) or search websites or blogs on the internet. Also, again, should there happen to be a newspaper article, internet article, or television or radio report relating to this case, do not read the article or watch or listen to the report. It is important that you decide this case based solely on the evidence presented in the courtroom. Please do not try to find out information from any other sources.

I know that many of you use cell phones, iPhones and other smartphones, iPads and other tablets, the internet, and other forms of technology. You must not talk to anyone about this case or use these tools to communicate electronically with anyone about the case. This includes your family and friends. You may not communicate with anyone about the case on your cell phone or smartphone, through e-mail, your tablet, text messaging, through any blog or website, through any internet chat room, or by way of any other social media or networking web sites, including but not limited to Facebook, X/Twitter, Instagram, TikTok, WeChat, WhatsApp, Snapchat, LinkedIn, and YouTube.

Finally, you should not form any conclusion as to the claims until all the evidence is in. Keep an open mind until you start your deliberations at the end of the case. You will receive detailed instructions on the law at the end of the case, and those instructions will control your deliberations and decision.

XIV. BENCH CONFERENCES AND RECESSES

During the trial it may be necessary for me to talk with the lawyers outside your hearing, either by having a bench conference while you are present in the courtroom, sometimes called a sidebar, or by me calling a recess. That may mean that some of the lawyers and I gather at sidebar so that we can talk.

If we have a bench conference, please understand that while you are waiting, the lawyers and I are working. And know that even then the parties are being charged for the time, *i.e.*, the time spent comes out of their total trial time. We are not trying to keep important information from you.

We will, of course, do what we can to keep the number and length of these conferences to a minimum. If you would like to stand or stretch or walk around the jury box while we are conferring, you should feel free to do so.

I may not always grant a lawyer's request for a conference. Do not consider my granting or denying a request for a conference as any indication of my opinion of the case or of what your verdict should be.

XV. COURSE OF THE TRIAL

Opening statements will begin on Monday, December 16, at 9:00 A.M.

Each side may make an opening statement. An opening statement is not evidence but is simply an outline of what that party intends to prove to help you follow the evidence that will be presented.

After the opening statements, the parties will present their evidence, according to the following general order.

First, Nippon Shinyaku will present its evidence that Nippon Shinyaku sustained damages as a result of Sarepta's infringement, and that the infringement has been and continues to be willful. To prove it is entitled to damages for patent infringement, Nippon Shinyaku must establish the amount of damages that it more likely than not has suffered. To persuade you that any infringement was willful, Nippon Shinyaku must also prove that it is more likely than not that the infringement was willful.

Nippon Shinyaku and NS Pharma will also present their evidence in support of their contentions that the asserted claim of the Wilton Patent is invalid. To prove invalidity of the claim, Nippon Shinyaku and NS Pharma must persuade you by clear and convincing evidence that the claim is invalid.

Second, Sarepta will present its evidence that the claims of the NS Patents are invalid. To prove invalidity of any claim, Sarepta must persuade you by clear and convincing evidence that the claim is invalid. Sarepta will present evidence responding to Nippon Shinyaku's evidence of patent damages, willfulness, and invalidity of the Wilton Patent.

Sarepta and UWA will also present their evidence that Sarepta and UWA sustained damages as a result of Nippon Shinyaku and NS Pharma's infringement, and that the infringement

has been and continues to be willful. To prove it is entitled to damages, Sarepta and UWA must establish the amount of damages that they more likely than not have suffered. To persuade you that any infringement was willful, Sarepta and UWA must also prove that it is more likely than not that the infringement was willful.

Third, Nippon Shinyaku will present evidence responding to Sarepta's evidence that the claims of the NS Patents are invalid and will respond to Sarepta's contentions of willfulness and damages related to the Wilton Patent.

Finally, after all of the evidence is presented, each side may make closing arguments. Closing arguments are not evidence. Their purpose is to summarize and interpret the evidence for you.

Both before and after closing arguments, I will give you instructions on the law and describe for you the matters you must resolve.

You will then retire to the jury room to deliberate on your verdict.

XVI. TRIAL SCHEDULE

Though you have heard this before, I want to again outline the schedule I will maintain during the course of this trial.

As I mentioned previously, opening statements will occur on Monday, December 16, 2024, and the case is expected to take up to five business days to try, so the trial presentation will go into Friday, December 20, 2024.

We will normally begin each day at 9:00 A.M and will end between approximately 4:30 and 5:00 P.M. The schedule will include a morning break of fifteen minutes, a lunch break of up to an hour, and an afternoon break of fifteen minutes.

What I have just outlined is the general schedule. It is possible there will be some interruptions if I have to attend to other matters.

The only significant exception to this schedule may occur when the case is submitted to you for your deliberations. At that point, you will be permitted to deliberate as late as you wish.

As I mentioned, this is a timed trial. That means I have allocated each party a maximum number of hours in which to present all portions of its case. This allows me to assure you that the trial is expected to be completed by Friday, December 20, 2024, although your deliberations could extend into the following week if you do not reach a verdict on Friday.

Of course, you can help us stay on schedule by being here promptly each morning and being ready to proceed at the end of each break.